OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 541710 Size Standard: 500 employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:*** [ ]
NIH-NIAID-DMID-03-06	[ ] Yes [X] No		

TITLE: In Vitro Antiviral Screening Program

Issue Date: ***September 30, 2002***	***Due Date:*** ***January 15, 2003*** ***Time:*** **4:00 PM, EST**	***Technical Proposal Page Limits:*** [X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:
Paul D. McFarlane
Senior Contracting Officer
Contact Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC7612
Bethesda, MD 20892-7612

[X] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:	***PERIOD OF PERFORMANCE:***
[ ] Only 1 Award [X] Multiple Awards	7 years beginning on or about 09/30/2003

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT **-- Karim Hourani** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

Telephone: Main **301-496-0612**	***Fax*** **301-402-0972**	***E-Mail*** **khourani@niaid.nih.gov**

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In Vitro Antiviral Screening Program
DMID-03-06

BACKGROUND

Viral infections are responsible for a substantial amount of morbidity and mortality. Although several antiviral drugs have been approved by the FDA for the treatment of a small number of non-HIV viral diseases, the majority of viral diseases remain untreatable. Accordingly, the discovery and development of clinically effective and non-toxic antiviral therapeutic agents are essential for the control of viral infections.

To date most of the licensed as well as experimental antivirals have been discovered by screening. However, many investigators at universities and small pharmaceutical firms who design and synthesize novel compounds, or who select, isolate and characterize new natural products do not have sufficient facilities and/or expertise to set up antiviral screens. In recognition of this need, in 1988, NIAID established a screening program to provide in vitro screens for evaluation of potential antiviral agents for inhibitory activity against herpes and respiratory viruses. This program was re-competed twice in the past, in 1993 and in 1998.

This new initiative is intended to re-compete the contracts currently awarded to University of Alabama at Birmingham (N01-AI-85347), Utah State University (N01-AI-85348), and Georgetown University (N01-AI-85349). The viruses provided by these three contractors are:

University of Alabama: herpes viruses (HSV-1, HSV-2, VZV, EBV, CMV, HHV-6, HHV-7, and HHV-8) and orthopoxviruses (vaccinia and cowpox virus)

Utah State University: respiratory viruses (influenza A, influenza B, parainfluenza-3, respiratory syncytial virus, measles, rhinoviruses, and adenovirus-5) and viral hemorrhagic fevers and encephalitis viruses (Venezuelan equine encephalitis, Pichinde, Punta Toro, yellow fever, and West Nile virus).

Georgetown University: hepatitis B virus, hepatitis C virus (small experimental scale, beginning in 2002)

The anthrax attack in 2001 dramatized the U.S. vulnerability to chemical or biological terrorist attack. The Government now must prepare a quick response with effective treatment and control measures to protect the civilian population in any future incidents. The most fearful biological agent is variola (smallpox) virus. In the 20th century alone, smallpox took 500 million lives, more than all the wars and epidemics combined. In 1972, believing the disease to be eradicated, the U.S. stopped routine vaccination. If smallpox strikes again, unleashed by war or terrorism, the traumatic consequence would be unthinkable. In 1999, as part of NIAID biodefense initiative, vaccinia virus and cowpox virus (in the same orthopoxvirus family as variola virus) were added to the screening program as the surrogate for smallpox. To date, several active compounds found in the program were also active against variola, as suggested by the in vitro studies by investigators of U.S. Army Medical Institute of Infectious Diseases (USAMRIID) working in the BL-4 facility at Centers for Disease Control and Prevention (CDC). Cidofovir is the most promising compound. Recently the DMID has filed three IND applications to the FDA proposing clinical trials of cidofovir for possible treatment of smallpox and as back-up treatment of vaccinia complications.

In addition to smallpox, viral hemorrhagic fevers and viral encephalitides are also regarded as possible biodefense organisms (for biodefense-related viruses, see http://www.bt.cdc.gov/Agent/Agentlist.asp and http://www.niaid.nih.gov/dmid/bioterrorism/bandc_priority.htm) In 1999, four representative viruses—Venezuelan equine encephalitis virus, Pichinde virus (an arenavirus like Lassa fever virus), Punta Toro virus (a bunyavirus like Rift Valley fever virus), and yellow fever virus—were also added to the screening program.

Because viruses included in the current contracts are of public health importance, screens against these viruses will continue with an expansion of research into hepatitis C virus (HCV) and human papillomaviruses (HPVs).

Hepatitis C virus (HCV), affecting millions of people worldwide, is a major cause of cirrhosis, end-stage liver disease, and liver cancer. Efforts to produce an effective vaccine are hampered by evasion due to continuous emergence of mutant viruses among other daunting reasons. For many years interferon-alpha has been the treatment for patients with chronic hepatitis C infection. However, it was successful in only 10-15% of patients with the lowest effects seen in patients infected with the most common genotype—genotype 1. Combination therapy with interferon-alpha and ribavirin significantly enhanced sustained virological response rates to 40%.

Pegylated interferons enhance interferon with longer half-life and more favorable pharmacokinetics. Combination of pegylated interferons and ribavirin leads to sustained response rates of about 50% with an acceptable safety profile. Thus effective therapies are still required. Recently the screening program has initiated a very small-scale experiment to explore replicon-based cell culture systems for anti-HCV drug discovery.

HPV, along with genital herpes, is one of the most common sexually transmitted diseases (STDs). An estimated 20 million Americans older than 14 suffer from HPV and an estimated 5.5 million new HPV infections occur among Americans each year. Several kinds of human tumors are associated with the various types of HPVs. Viral DNA is frequently detected in anogenital tumors, such as the genital wart of the cervix, vulva, and anus. The juvenile-onset laryngeal papillomatosis, thought benign, is resistant to treatments, recur frequently, and tend to spread through the respiratory tract. Treatments of HPV infections by injection of interferon and cidofovir have been reported. Although the favorable response occurred in a proportion of patients, recurrence after the cessation of treatment was not uncommon.

The objective of these in vitro screens is multi-faceted: (1) Selective indexes of potential antiviral compounds are determined to guide the selection and prioritization of compounds for evaluations in animal models; (2) Active compounds are further evaluated against several virus strains including clinical and drug-resistant isolates to explore their clinical potential; (3) When appropriate, studies on mechanisms of action and drug combinations are conducted to better understand compounds' pharmacological properties, as well as potential utilization and limitations (e.g., virustatic vs. virucidal activity, systemic vs. topical treatment, synergistic vs. antagonistic drug interaction); and (4) Research also is conducted to improve the current screening systems, to develop automated high-throughput screening systems, and to adopt new assays.

Investigators in the antiviral research community have enthusiastically utilized the in vitro screening program. This program has helped identify and prioritize compounds for further studies in NIAID-supported animal models. A number of them are progressing in different stages of preclinical development. In addition, the data obtained from the screens have supported the IND applications for several compounds.

Until clinically proven safe and effective antiviral therapies have been identified for each of the serious viral infections that afflict mankind, it is clear that continued efforts to identify antiviral substances by screening are needed. This recompetition is planned to assure the continuation of this vital resource for the identification of antiviral agents.

Statement of Work
In Vitro Antiviral Screening Program
RFP DMID-03-06

There are seven principal viral categories covered under this RFP: (1) herpes viruses, (2) respiratory viruses, (3) hepatitis B virus, (4) hepatitis C virus, (5) human papillomaviruses, (6) orthopoxviruses, and (7) biodefense pathogens (or their surrogates) that cause viral hemorrhagic fever and/or encephalitis. A single Offeror may submit proposals for one or more principal viral categories, but must submit separate and distinct business and technical proposals for each proposed viral category. In addition, or each principal viral category, an Offeror may propose one or more assays for a single virus (e.g., virus/assay systems such as HSV-1/CPE assay and HSV-1/plaque reduction assay). Each assay pertaining to a single virus should be clearly marked in the Technical Proposal so as to facilitate the technical review of that virus/assay system.

Each principal viral category will be scored separately and a competitive range will be determined for each. Awards will be made on the basis of the technical merit of each principal viral category as determined through peer review, the relevance and uniqueness of each virus/assay system in relation to Program priorities and balance, and the availability of funds. It is the intent of the Government to make at least one award for each principal viral category. However, the Government reserves the right to make one award, multiple awards, or no award in each principal viral category, which may or may not include all of the proposed virus/assay systems, based on overall programmatic need. It is possible that during negotiations an Offeror will be asked to delete one or more virus/assay systems from their proposal if they are not considered to be relevant to the project objectives.

STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified professional and technical personnel, material, equipment, and facilities needed to perform the work set forth below.

Specifically, the Contractor shall:

(1) Provide validated screening systems for all of the selected viruses. Conduct evaluation on experimental antiviral substances using proven assays. (See Notes to Offerors A, B, C)

a. Determine the inhibitory effect on virus replication and/or infectivity based on meaningful endpoints, such as, but not limited to, 50% and/or 90% effective and cytotoxic concentrations and selective indexes. Evaluations shall incorporate both the substance under investigation and a positive control agent.

b. Determine the inhibitory effect against other virus strains (e.g., clinical isolates, drug-resistant strains) in appropriate cell lines, as determined by the Project Officer, for compounds with reasonable selective antiviral activity identified in Work Statement 1.a.

(2) Perform special studies as directed by the Project Officer, which shall include, but are not restricted to, combination drug testing, mechanism of action studies targeting specific steps in viral replication, and other more detailed testing. As requested by the Project Officer, assays pertinent to special studies shall be designed, developed, compared to existing assays, standardized, validated and performed, as necessary. (See Note to Offeror D)

(3) Evaluate and develop new in vitro testing systems at the direction of the Project Officer. (See Note to Offeror E)

(4) Receive, Store, and Record substances for testing. (See Note to Offeror F)

a. Maintain and store frozen stocks of compounds in a sterile manner.

b. Maintain a master list of compounds received for testing, freezer location, usage, and other pertinent information.

(5) Conduct works in accordance with all applicable Federal, State, and Local safety and health guidelines and regulations regarding to exposure to hazardous chemicals and potentially harmful and/or infectious biological materials. Safety and Health HHSAR 352.223-70 clauses shall apply. (See Notes to Offerors G and H)

(6) Abide by terms of the Screening Agreement with drug sponsors signed by the DMID Director. Maintain all confidential data in files accessible only by the Principal Investigator and involved staff. (See Notes to Offerors I and J)

(7) Communicate effectively with the Project Officer, other contractors, and investigators. (See Notes to Offerors K and L)

a. Establish a means of electronic communication with the Project Officer sufficient to support daily exchange of e-mail and the submission of data files and interim reports when requested.

b. Submit a screening report for each substance tested in accordance with the Technical Reporting Requirements contained in the contract. The screening report shall contain the Contractor's recommendations and explanations as to (i) whether or not a substance warrants further studies and, if applicable, (ii) specific additional studies to be performed.

c. Provide advance copies of draft manuscripts for publication (including abstracts and public presentations) based on data generated under the contract to the Project Officer, and obtain clearance before submitting for publication or presentation. Support from the Government must be acknowledged in all abstracts, presentations, and publications.

d. Participate in the annual meeting of the Collaborative Antiviral Testing Group (CATG). Biodefense-related contractors shall participate in an additional annual biodefense research meeting.

Notes To Offerors
In Vitro Antiviral Screening Program
DMID-03-06

NOTE TO OFFEROR (A): It is expected that 1500 experimental antiviral substances will be evaluated against orthopoxviruses and pathogens of viral hemorrhagic fever and encephalitis, 10 against human papillomaviruses, and 200 against viruses from the other viral categories annually. The drug sponsors will supply the test substances after receiving approval from the Project Officer. Acquisition of test substances will come from NIAID's TB Antimicrobial Acquisition and Coordination Facility (contract N01-AI-95364, Southern Research Institute), NIAID staff contacts with drug sponsors, and screening contractors' contacts with drug sponsors. These substances may be irritating, toxic, and/or potentially carcinogenic or hazardous. Back to Item 1 of Statement of Work

NOTE TO OFFEROR (B): The Offeror shall provide validated screening systems for all of the designated viruses within the category(ies) selected. Methods of screening shall be appropriate for the assessment of the efficacy of potential therapeutic and/or prevention approaches for the proposed viruses. The methods may include, but are not limited to, plaque reduction, yield reduction, inhibition of cytopathic effect, inhibition of enzyme activity and other virus-specific assays. Assays can be manual or automatic format. Offerors shall justify the choice of method(s) proposed.] Back to Item 2 of Statement of Work

NOTE TO OFFEROR (C): More detailed testing will generally be required when the initial screening shows that an a substance has a substantial level of antiviral activity. The technical proposal shall describe preliminary screening procedures, the criteria used to select compounds recommended for further evaluation, and procedures for the special studies identified in Work Statement 2 below. Back to Item 3 of Statement of Work

NOTE TO OFFEROR (D): Each special study will have distinctive evaluation needs; thus, the Project Officer will designate specific assays after consultation with the Contractors. The Offeror should include documentation of qualifications, expertise, and strategies to modify systems or develop new systems for such studies. Provide 1-2 examples of the types of special studies that could demonstrate Offeror's capability. It is expected that special studies will be performed on no more than 30 compounds per year for orthopoxviruses and pathogens of viral hemorrhagic fever and encephalitis, one against human papillomaviruses, and 5 against viruses from the other viral categories annually. Back to Item 4 of Statement of Work

NOTE TO OFFEROR (E): It is expected that no more than 10% effort of the proposed professional staff will be utilized per year to perform these evaluation. Back to Item 5 of Statement of Work

NOTE TO OFFEROR (F): The technical proposal shall provide detailed information about how this Work Statement will be addressed and identify other factors thought to be pertinent. Back to Item 6 of Statement of Work

NOTE TO OFFEROR (G): The technical proposal shall specify procedures that demonstrate that the Offeror understands and will comply with these Federal, State, and Local guidelines and regulations. Federal guidelines related to workplace safety can be viewed at http://www.nih.gov/od/ors/ds/safetymgt.html. A Safety and Health Plan shall be in place for compliance. The Plan shall include discussions of such topics as training and monitoring of personnel, the use of protective garments and equipment by personnel, and protocols for dealing with chemical and biological spills and accidents. The technical proposal shall also describe how to manage both short-term and long-term storage of infectious materials, receiving and shipping infectious materials and potentially hazardous chemicals, etc. Back to Item 7 of Statement of Work

NOTE TO OFFEROR (H): The Offeror shall, at the time of the proposal have appropriate biosafety laboratory facilities that allow research using the viruses that are assigned to the respective biosafety levels (for reference see, Biosafety in Microbiological and biomedical Laboratories, 4th Ed., May 1999, by CDC and NIH). If the proposed virus is a BSL-3 agent, at the time of award, BSL-3 facilities must be operational. Back to Item 5 of Statement of Work

NOTE TO OFFEROR (I): See Section J-List of Attachments - Planned Deviation to Required General Clauses 52.227-11 and 52.227-14. Back to Item 7 of Statement of Work Planned Deviation to Required General Contract Clauses 52.227-11 and 52.227-11. By providing information on antiviral activity developed under these contracts to suppliers of testing substances, the NIAID seeks to stimulate research and development in all sectors of the antiviral scientific community.

Because the goal of this NIAID in vitro antiviral screening program is to promote the determination of critical biological information, it will be necessary to restrict certain rights of the contractor providing in vitro testing to either attract suppliers of proprietary compositions or enable NIAID to offer a package of intellectual property rights to a collaborator for commercialization. It is anticipated that the great majority of substances submitted to the NIAID for testing will be

proprietary in nature, and our experience has demonstrated that suppliers are reluctant to provide testing substances or ideas without complete assurance that their intellectual property rights are protected. In addition to the need to protect third party suppliers' proprietary rights, it is also necessary to consolidate into a single package the intellectual property rights that may arise in the performance of multiple contracts within this NIAID program.

Thus, the NIAID plans to seek a deviation from FAR clause 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989). Pursuant to a Determination of Exceptional Circumstances (DEC) as required by FAR 27.303, the NIAID plans to modify clause at FAR 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989) to restrict the contractor's rights to subject inventions arising under the contract. Specifically, the contractor will be required to assign to the Government or, if deemed appropriate by the NIAID and subject to certain rights reserved to the Government, to a collaborating party designated by the Government the entire right, title and interest throughout the world to each subject invention, except to the extent that rights are retained by the Contractor under the Greater Rights Determination provision of the clause. The contractor may request greater rights to an identified invention, and the NIH will consider whether granting the requested rights will interfere with rights of the Government or any collaborating party or otherwise impede the ability of the Government or others to develop new candidates for therapies, disease prevention and diagnosis as well as potential enabling technologies that may result from data ensuing from evaluations performed under this contract useful for antiviral discovery and development. Contractors are encouraged to request greater rights where inventions relate to technology outside NIAID's program and where the contractor has negotiated with a supplier of a proprietary composition for the disposition of patent rights concerning a subject invention related to the composition.

Furthermore, the timing of data publication will need to be restricted to allow adequate time for patent applications to be filed on inventions arising from the contracts. This would be accomplished by a deviation from FAR clause 52.227-14, Rights in Data-General (June 1987). Specifically, although NIAID encourages the publication of articles on research results, FAR 52.227-14 Rights in Data-General (June 1987) will be narrowly modified to restrict the Contractor's right to use, release to others, reproduce, distribute, and publish data produced or used by the contractor in the performance of this contractor allow adequate time for the filing of patent applications and to protect data that will be submitted as part of a regulatory filing. NIAID will reserve the right to coordinate the timing of data publication so that appropriate domestic and international invention applications may be filed as appropriate.

Potential Offerors are advised that a Determination of Exceptional Circumstances (DEC) signed by the Director, NIH, along with the aforementioned FAR clause deviations will be sought for this initiative. Because these clause deviations are not yet approved, their text is not available for publication. (However, it is NIAID's intention that the finalized versions of the deviated FAR clauses will be available before award of any contract resulting from this initiative.) Instead, the aforementioned description of how these clause deviations will be practiced under the resultant contract is provided. Potential Offerors are afforded an opportunity to comment on their understanding of what NIAID is planning and to identify what impact these deviations may have on their conduct of the work should they be awarded a contract. Responses should be provided, in writing, to the Point of Contact for this RFP. See the bottom of the front page of this RFP for this individual's name and contact information. Comments should be provided within 30 days of the issue date of this RFP. Thereafter, NIAID will consider this input and determine whether alternative courses of action may be necessary. Decisions regarding these deviations will be made in consideration of the success of this NIAID requirement.

NOTE TO OFFEROR (J): The technical proposal shall specify procedures to safeguard all information associated with the substances being tested, such that no identifiable data on the compounds or products and the results of testing will be kept in files open to the public. Facilities for computer operation, data entry, and file storage should be secure from unauthorized access. Back to Item 1 of Statement of Work

NOTE TO OFFEROR (K): The Project Officer will review the screening report and forward it to the compound sponsor. The technical proposal shall include a template of the proposed data sheet to be included in the screening report. Back to Item 1 of Statement of Work

NOTE TO OFFEROR (L): Costs to support travel to the CATG and biodefense meetings for Principal Investigator, and a designated Co-Investigator (if desired), should be included in the proposed cost estimate. For estimating purposes assume that each meeting will be held for two full days in Bethesda, MD Back to Item 1 of Statement of Work

Reporting Requirements
In Vitro Antiviral Screening Program
RFP DMID-03-06

The Contractor shall submit to the Contracting Officer (CO) and the Project Officer (PO) technical progress reports covering the work accomplished during each reporting period. The exact submission schedule will be negotiated and established in the contract document. These reports shall be factual and prepared in accordance with the following format:

A. Monthly Technical Progress Reports - The Contractor shall submit four (4) copies 7 calendar days following the end of each month of the project. Each monthly report shall consist of:

1. A cover page containing:

- Contract number and title
- Period of performance being reported
- Contractor's name and address
- Author(s)
- Date of submission

2. Screening data sheets for all compounds tested during the month.

3. A updated list of received compounds including NIAID's codes, compound names, compound sponsor names and institutions.

4. A summary section containing discussion and recommendations to facilitate planning for further studies or for reporting to the compound sponsor.

5. A high-density floppy disk containing all information recorded on the monthly screening report (section A.2). The stored information shall be retrievable by using Microsoft Excel spreadsheet program.

B. Semi-annual Technical Progress Report - The Contractor shall submit three (3) copies of semi-annual report 30 calendar days following the end of each sixth month period. In addition to the cover page described in section A.1, each report shall include:

1. SECTION I - An introduction covering the purpose and scope of the contract effort.

2. SECTION II - A description of overall progress plus a separate description of each task or other logical segment of work on which effort was expended during the report period. Descriptions shall include pertinent data and graphs in sufficient detail to explain any significant results achieved and a scientific evaluation of the data accumulated to date under the contract.

3. SECTION III- Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have occurred and if behind planned progress what corrective steps are planned.

4. An anticipated work plan for the next reporting period.

Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due.

C. Annual/Final Reports - The Contractor shall submit three (3) copies of the annual and final reports, as outlined in item B., which detail, document, and summarize the results of the entire contract work for the period covered. These reports shall be in sufficient detail to comprehensively explain the results achieved. Annual reports shall be submitted 30 calendar days following the anniversary date of the contract. The final report shall be submitted by the completion date of the contract. An annual report is not required for the period when the final report is due.

D. Summary of Salient Results - With the final report, the Contractor shall submit a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

E. If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

F. TECHNICAL REPORT DISTRIBUTION

Copies of the technical reports shall be submitted as follows:

Type of Report	No. of Copies	Address	Due Dates
Monthly	3	Project Officer DMID, NIAID, NIH 6700B Rockledge Dr. Bethesda, MD 20892-7630	Monthly (Specific dates will be listed in the contract document.)
Monthly	1	Contracting Officer Room 2230 CMB, NIAID, NIH 6700B Rockledge Dr. Bethesda, MD 20892-7612	Same as above
Semi-Annual	2	Same as PO above	Semi-annually (Specific dates will be listed in the contract document.)
Semi-Annual	1	Same as CO above	Same as above
Annual	2	Same as PO above	Annually (Specific dates will be listed in the contract document.)
Annual	1	Same as CO above	Same as above
Final	2	Same as PO above	Completion date
Final	1	Same as CO above	Same as above

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs

52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 05/2002]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PLANNED DEVIATION TO REQUIRED GENERAL CONTRACT CLAUSES FAR 52-227-11 & FAR52.227-14 (Attached to this listing)
PACKAGING AND DELIVERY OF PROPOSALS: (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: Friday, December 6, 2002 (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Summary of Related Activities**
- **Project Objectives, NIH-1688-1**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-1: Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH-2706: Financial Report of Individual Project Contract**
- **Instructions for Completing Form NIH-2706**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP-NIH-NIAID-DMID-03-06 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 150 PAGES [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":

Approximately TWO weeks prior to the due date of the proposals, all offerors who submitted a "Proposal Intent Response Sheet" will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided via telephone by the Contract Specialist after Log-in Name is provided.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-03-06
RFP Title: In Vitro Antiviral Screening Program
OFFOEROR TO IDENTIFY PRINCIPAL VIRAL CATEGORIES: for which they intend to submit proposal(s).

Please review the attached Request for Proposal. Furnish the information requested below and return this page by Friday, December 6, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Ross Kelley
RFP-NIH-NIAID-DMID-03-06
FAX# (301) 402-0972
Email : rk17a@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.nci.nih.gov/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
(2) The small business size standard is 500.

b. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that MULTIPLE AWARD(S) will be made from this solicitation and that the award(s) will be made on/about September 30, 2003.

It is anticipated that the awards from this solicitation will be multiple-year cost reimbursement type completion contracts with a seven-year period and that incremental funding will be used. See Section L.2.c. Business Proposal Instructions.

c. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

d. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

e. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

f. **COMPARATIVE IMPORTANCE OF PROPOSALS**

The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

g. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

h. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

2. INSTRUCTIONS TO OFFERORS

GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a [cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

a. Project Objectives, NIH-1688-1

The Offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an Institution of Higher Education: The form MUST be completed in its entirety.
- For OTHER than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "INSTRUCTIONS:"

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which

may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(9) **Selection of Offerors**

a) The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily and FedBizOpps.

(10) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24,

(11) **Prohibition on Contractor Involvement with Terrorist Activities**

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

(12) **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(3) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the

Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

(4) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(5) Proposer's Annual Financial Report

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(6) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(7) Travel Costs/Travel Policy

a) **Travel Policy**

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more Offerors are determined to be essentially equal following the evaluation of all factors other than cost/price. In any event, the Government reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

There are seven principal viral categories covered under this RFP: (1) herpes viruses, (2) respiratory viruses, (3) hepatitis B virus, (4) hepatitis C virus, (5) human papillomaviruses, (6) orthopoxviruses, and (7) biodefense pathogens (or their surrogates) that cause viral hemorrhagic fever and/or encephalitis. A single Offeror may submit proposals for one or more principal viral categories, but must submit separate and distinct business and technical proposals for each proposed viral category. In addition, for each principal viral category, an Offeror may propose one or more assays for a single virus (e.g., virus/assay systems such as HSV-1/CPE assay and HSV-1/plaque reduction assay). Each assay pertaining to a single virus should be clearly marked in the Technical Proposal so as to facilitate the technical review of that virus/assay system.

Each principal viral category will be scored separately and a competitive range will be determined for each. Awards will be made on the basis of the technical merit of each principal viral category as determined through peer review, the relevance and uniqueness of each virus/assay system in relation to Program priorities and balance, and the availability of funds. It is the intent of the Government to make at least one award for each principal viral category. However, the Government reserves the right to make one award, multiple awards, or no award in each principal viral category, which may or may not include all of the proposed virus/assay systems, based on overall programmatic need. It is possible that during negotiations an Offeror will be asked to delete one or more virus/assay systems from their proposal if they are considered to not be relevant to the project objectives.

Offerors must submit separate technical and business proposals for each viral category they wish to apply to.

2. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent of commitment to use SDB concerns
(b) Complexity and variety of the work SDB concerns are to perform
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERA	**WEIGHT**
SCIENTIFIC CONSIDERATIONS	**60 Points**

1. Assay Systems (25 Points)

Applicability and suitability of the proposed assay systems and protocols for evaluation of potential antiviral substances against the proposed viruses.

2. Working Plan (35 Points)

Adequacy and feasibility of the proposed plans and strategies for evaluation of antivirals and the accomplishment of all the objectives of the Work Statement within an appropriate proposed time frame.

PERSONNEL and MANAGEMENT	**25 Points**

1. The Team (15 Points)

Documented evidence of the qualifications, experience, and availability of all technical personnel in working with infectious diseases and antiviral research, in relation to their proposed roles.

2. The Principal Investigator (10 Points)

The same qualification as above plus experience in managing complex projects of a similar nature. Documentation regarding experience in interaction with antiviral community, adequacy of the management plan and mix of staff, and organizational structure for the conduct of the project.

FACILITIES	**15 Points**

Documentation regarding the availability and adequacy of the facilities and equipment to carry out the studies proposed.

TOTAL:	**100 Points**

Agreement for Submitting Products to the Division of Microbiology and Infectious Diseases, NIAID, NIH for Antiviral Screening

The Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases (DMID, NIAID), an institute of the National Institutes of Health, which is a component of the U.S. Public Health Service, an agency of the U.S. Government, offers antiviral screening services, through contract testing laboratories, to for-profit and non-profit organizations to help facilitate the rapid development and commercialization of products for the treatment of viral diseases other than AIDS. The COMPANY would like to submit its product(s) for antiviral screening. Therefore, the COMPANY and DMID, NIAID agree as follows:

1. **Restricted Use of COMPANY Product(s).** COMPANY may submit product(s), patented or unpatented, to DMID, NIAID for the purpose of being evaluated for antiviral activity *in vitro* by one or more testing laboratories under contract with the DMID, NIAID (hereinafter "contractor(s)"). DMID, NIAID agrees that the product(s) will be evaluated only in accordance with known testing protocol(s) by its contractor(s), as approved by COMPANY, as agents with potential for the treatment or prevention of infectious diseases and for no other purpose. The product(s) will not be transferred to any party other than the approved contractor(s). In addition, the product(s) will not be chemically modified, replicated, derivatized or reverse engineered unless required by the approved testing protocol or otherwise approved in writing by COMPANY.

2. **Confidentiality.** Information, data and records will be handled as follows:

   a. COMPANY shall forward to the Virology Branch (VB) or Enteric and Hepatic Diseases Branch (EHDB) of the DMID, NIAID or, as directed by either the VB or the EHDB, to the contractor(s) the data sheet(s) on the product(s) to be evaluated, marked "confidential". COMPANY shall provide duplicate copies of the data sheet(s) for each product, which shall include all pertinent available data as to chemical composition, solubility, toxicity, etc. and any precautions that should be followed in handling, storing and shipping the product. For those products in which COMPANY has a proprietary interest but does not yet have adequate patent protection, COMPANY may, in rare cases and with approval by DMID, NIAID, submit a product(s) under code number(s) only. In these cases, COMPANY agrees to reveal to DMID, NIAID and its contractor(s) the structures or identities of the coded product(s), marked "confidential", which subsequently turn out to be positive in any one of the test systems. The structures or identities of such product(s) will remain confidential in accordance with Section 2b below.

   b. COMPANY may provide to DMID, NIAID and/or its contractor(s) any scientific, business or financial information relevant to the product(s) that COMPANY deems to be its proprietary and confidential information. COMPANY must identify such information as confidential. To the extent permitted by law, this information will remain confidential for five (5) years from the date of disclosure unless:

      (1) the information is known by the public or becomes known by the public through no fault of DMID, NIAID or its contractor(s);

      (2) the information was obtained by DMID, NIAID or its contractor(s) from a third party having no confidentiality obligation to COMPANY;

      (3) the information was made available to DMID, NIAID or its contractor(s) by COMPANY without a confidentiality obligation;

      (4) the information has been independently developed by DMID, NIAID or its contractor(s) without reference to COMPANY's information; or

      (5) the information is required to be disclosed by law, regulation or court order provided that COMPANY has been notified and DMID, NIAID and/or its contractor(s) have taken reasonable efforts to minimize the extent of the required disclosure.

   c. DMID, NIAID agrees that information or data about the product(s), including the evaluation results, will be kept in restricted-access files by DMID, NIAID and the contractor(s). Only employees of DMID, NIAID or its contractor(s) will have access to the files containing information about the product(s) including the

evaluation results. COMPANY acknowledges that the evaluation results are not its confidential information and may be disclosed by DMID, NIAID and/or its contractor(s) *only* in accordance with Section 3b below.

d. The contracts between DMID, NIAID and the testing laboratories require the contractor(s) to abide by the terms of this Agreement.

e. DMID, NIAID will use its best efforts to assure rapid ongoing communication of the evaluation results to COMPANY and, in turn, COMPANY will use its best efforts to keep DMID, NIAID up-to-date on COMPANY's own ongoing concomitant studies.

3. **Intellectual Property and Publications.** COMPANY recognizes that the exchange of biological data and other information is generally desirable in the field of antiviral treatment, and DMID, NIAID recognizes that COMPANY, is entitled to protection for its research and development work on the product(s) and its related technical information. Therefore:

a. Intellectual Property. DMID, NIAID agrees that all right, title and interest in and to all products and information provided by COMPANY to DMID, NIAID under this Agreement will remain with COMPANY. DMID, NIAID acknowledges that this Agreement may not be construed as a grant by COMPANY of a license or any other right or interest beyond those expressly set forth herein. The contracts between DMID, NIAID and its testing laboratories require the contractor(s) to assign to COMPANY all right, title and interest in and to any invention made during the evaluation that directly relates to COMPANY's product(s). For purposes of this Agreement the phrase "directly relates to" means "contains, in whole or in part, COMPANY's product(s)" and/or any new use of COMPANY's product(s).

b. Publications. COMPANY and DMID, NIAID agree that the publication of biological data on COMPANY's product(s) evaluated under this Agreement is worthwhile and to be encouraged. Therefore:

(1) COMPANY agrees that DMID, NIAID and/or its contractor(s) may publish or otherwise publicly disclose the evaluation results after a period of six (6) months from the date the evaluation results are reported to COMPANY. Publication of data within the six (6) month period will require COMPANY'S prior consent, which shall not be unreasonably withheld. DMID, NIAID and/or its contractor(s) shall not publish information identifying COMPANY as the source of the product(s) without COMPANY's prior written approval.

(2) As soon as the evaluation(s) is/are completed and reported by the contractor(s) to the VB or EHDB of DMID, NIAID, COMPANY will receive a full report of the evaluation(s). COMPANY agrees to consult the VB or EHDB of DMID, NIAID whenever COMPANY desires to include the evaluation results in any publication or other public disclosure such as a press release, and shall give appropriate credit to the U.S. Public Health Service and the DMID, NIAID's contractor(s) that performed the evaluation(s). COMPANY shall not construe the involvement of DMID, NIAID or its contractor(s) in the evaluation(s) as an endorsement of the product(s) by the U.S. Government or any of its agencies or employees.

4. **Liability and Indemnification.** Each Party shall be liable for any loss, claim, damage, or liability that it incurs as a result of its activities under this Agreement except that the NIAID, as an agency of the U.S. Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Ch. 171. No indemnification is provided by either Party under this Agreement. The NIAID is prohibited under statute, the Anti-Deficiency Act, 31 U.S.C. § 1341, from indemnifying any party, absent other specific statutory authorization.

If COMPANY agrees to the terms above, please have an authorized representative countersign below and return one fully signed original to the Division of Microbiology and Infectious Diseases, NIAID.

National Institute of Allergy and Infectious Diseases

Carole Heilman, Ph.D.
Director, Division of Microbiology & Infectious Diseases
NIAID, NIH

Date

COMPANY

Signature of Authorized Representative

Printed/Typed Name

Name of Company

Address of Company

Date